

EFFICACY EVALUATION-TEAM 2
RISK ASSESSMENT & SCIENCE SUPPORT BRANCH
ANTIMICROBIAL DIVISION

Date In: 11-17-97 Date Out 02-20-98

EPA Received Date: 11-17-97

RASSB Received Data: 12-09-97

Reviewed by: Bruce H. Mann Microbiologist

Lan Code: 1677-129.298

EPA Reg. No. or File Symbol 1677-129

Product Name Oxonia Active

Product Type Sterilant/Hospital Disinfectant/Sanitizer (for FCS)

Company Name EcoLab., Inc.,

MRID No (s): 444274-01, 444274-02, and 444274-03.

PM Team /Reviewer : PM-33 Swindel/Kish

Submission Purpose: An amendment with efficacy data in support of label claims for additional test microorganisms, non-food contact sanitizing data, and sanitizing data (for food contact surfaces).

Product Formulation A liquid concentrate to be diluted for use.

<u>ACTIVE INGREDIENT (S)</u>	<u>%</u>
Hydrogen Peroxide	27.50
Peroxyacetic Acid	5.80

200.0 Introduction

200.1 Use (s)

Refer to the proposed attached labeling pinpunched 11-17-97 and the last accepted label dated 06-19-96.

200.2 Background Information

The product "Oxonia Active" is a registered as a sterilant, hospital disinfectant and as a food contact surface sanitizer.

The current submission received 01-29-98 is an amendment to add additional test microorganisms, and to upgrade the product proposed label.

201.0 DATA SUMMARY
None

201.1 BRIEF DESCRIPTION OF TESTS

- A. "Oxonia Active"-Supplemental Food Contact Surface Sanitizing Efficacy Data". Data were developed by the AOAC Germicidal and Detergent Sanitizing Method. Efficacy- by Pamela J. Reed, Ecolab Inc., 840 Sibley Memorial Hwy, Mendota Heights, MN 55118, dated 04-01-97. (MRID #444274-02).
- B. "Oxonia Active with liquid K" -Supplemental Non-Food Contact Surface Sanitizer for precleaned, non-food contact surface sanitizer by John D. Hilgen, Ecolab Inc., 840 Sibley Memorial Hwy, Mendota Heights, MN 55118, (MRID #444274-01).
- C. "Oxonia Active" -Supplemental Efficacy with Additional Tests Organisms, by Kellen M. Glutzman, Ecolab., Inc., 840 Sibley Memorial Hwy, Mendotal Heights, Mn 55118, dated 04-01-97. (MRID #444274-03).

201.3 Data Summaries:
None.

201.4 Other Summarized Results:
Refer to Efficacy Part II, and note 202.0 under recommendations.

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Project Return Date: 02-20-98

Review Start Date: 02-12-98

Review Completion Data: 02-20-98

MRID No (s): 444274-01, -02, -03,

Product Manager/Reviewer & Team No. : PM-33 Swindel/Kish

Product Name: Oxonia Active

Company Name: Ecolab., Inc.,

202.0 Recommendations

202.0 Claims Related to Human Health

202.1 Efficacy Supported by the Submitted Data

- A. The submitted microbiological data developed by the AOAC Use Dilution Test Method 16th edition are supportive of the product effectiveness as a disinfectant at a dilution of 0.30% in the presence of synthetic hard water (500 ppm) ,in the presence of 5% fetal bovine serum and the presence of 0.005% artificial residue (sodium stearate) for hard, nonporous, inanimate surfaces are which thoroughly wetted and allowed to remain wet for a 10 minute exposure.

Effectiveness was demonstrated against Salmonella enteritidis, Salmonella typhimurium, Proteus vulgaris, and Streptococcus pyogenes under the above test conditions.

- B. The submitted data developed by the Germicidal and Detergent sanitizing Method are acceptable in support of the product as a sanitizing rinse at a dilution of 1 oz/4 gallons in 500 ppm of synthetic hard water for food contact surfaces that have been thoroughly precleanaed, rinsed with clear water and followed with the terminal sanitizing solution for a 30 second exposure time at 25.0°C.

Effectiveness was demonstrated against Escherichia coli strain (O157:H7).

- C. The submitted data also are supportive of the product as sanitizer for precleaned hard non-food contact surfaces after 30 seconds at ambient temperature when combined with Liquid K (1 oz/6 gallons) (0.13%) and when applied as a foam consisting of a dilution of 1oz/4 gallons (0.20%) of product in 500 ppm of synthetic hard water 500 ppm for a 30 second exposure time at 23.3°C to 25.2°C.

Effectiveness was demonstrated against Staphylococcus aureus, Enterobacter aerogenes, Listeria monocytogenes under the above test conditions.

202.3 Additional Data Required to Support Efficacy

The applicant needs to provide the agency with a composition of the product listed as "liquid K". Liquid K was used in combination with "Oxonia Active" to form the foam sanitizing solution for nonfood contact surfaces.

This information and clarification are needed to complete the review for the current submission.

203.0 Labeling Comments

The proposed comments are applicable for the product "Oxonia Active", pinpunched 11-17-97.

- A. There are no adverse comments on page #1.
- B. Page #2 contains no adverse comments.
- C. On page #3, there are no adverse comments.
- D. Page #4 contains no adverse comments.
- E. There are no adverse labeling comments on page #5.
- F. The applicant needs to provide the agency with a composition of the product listed as "liquid K". Liquid K was used in combination with "Oxonia Active" to form the foam sanitizing solution for nonfood contact surfaces.
This information and clarification are needed to complete the review for the current submission.